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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/827,271      | 04/04/2001  | Marc W. Retter       | 210121.462C6        | 4618             |

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EXAMINER

TUNG, JOYCE

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1637

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/827,271

Applicant(s)

RETTET ET AL.

Examiner

Joyce Tung

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-2 and 9-10, drawn to an isolated O8E polypeptide comprising a sequence set forth in any one of SEQ ID NO: 392 and 393 and the fusion protein with the polypeptide and the composition containing the sequence and the fusion protein, classified in class 530, subclass 350.
  - II. Claim 3, drawn to an antibody epitope of O8E wherein the antibody epitope is selected from the group consisting of amino acid residues 61-80 of SEQ ID NO:392 and amino acid residues 151-170 of SEQ ID NO: 392, classified in class 530, subclass 388.1.
  - III. Claim 4, drawn to an O8E peptide that is selected from the group consisting of SEQ ID NO: 416-455, classified in class 530, subclass 350.
  - IV. Claims 5 and 9-10, drawn to an isolated O772 polypeptide comprising a sequence set forth in any one of SEQ ID NO: 312, 388, 389 and 390, the fusion protein with the polypeptide and the composition containing the sequences and the fusion protein, classified in class 530, subclass 350.
  - V. Claims 6 and 10, drawn to an isolated antibody and the composition containing the antibody, classified in class 530, subclass 388.1.
  - VI. Claims 7 and 10, drawn to an isolated antibody and the composition containing the antibody, classified in class 530, subclass 388.1.

- VII. Claim 8, drawn to a method for detecting the presence of a cancer via polypeptide, classified in class 435, subclass 7.
- VIII. Claim 11 is drawn to a method for stimulating an immune response in a patient, classified in class 530, subclass 387.1.
2. The inventions are distinct, each from the other because of the following reasons:
- a. Inventions I-VI and VII-VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the products groups are drawn to polypeptide and antibody which be used in an enzymatic reaction or immuno-assay.
- b. Inventions I-VI are distinct. Groups I and III-IV are all drawn to an isolated protein, while Groups II and V-VI are drawn to an isolated antibody. Protein and antibody consist amino acid sequences. However, the biochemical structures between the antibody and protein are different and they have different utilities, for example, the protein can be used in an enzymatic reaction and the antibody can be used in an immuno assay. Thus, Groups I and III-IV, and Groups II and V-VI are distinct from each other.
- c. Among Groups I and III-IV, although they are drawn on proteins, they have different amino acid sequences as set forth in claim 1 and 4-5. Thus, they are distinct from each other.

d. Among Groups II and V-VI which are drawn to isolated antibodies. However, these antibodies have different specificities when they bind to a probe or polypeptide as set forth in claims 3 and 6-7. Thus, they are different inventions.

e. Inventions VII and VIII are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, Invention VII is drawn to a method of detecting the presence of a cancer via polypeptide, while Invention VIII is drawn to a method for stimulating an immune response in patient. Thus they have different modes of operation, different functions, or different effects. Therefore, they are distinct from each other.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. These claims are generic to a plurality of disclosed patentably distinct restriction groups comprising different SEQ ID NOs. Applicant is required under 35 U.S.C. 121 to elect no more than 1 disclosed amino acid sequence even though this requirement is traversed.

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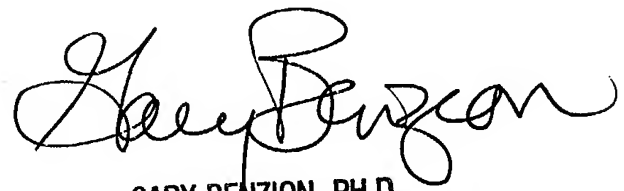
Should applicant traverse on the ground that some or all of the different nucleic acids are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the nucleic acids to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is 703 (305) 7112. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703 308 1119. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 (308) 0196.

Joyce Tung *ET*  
September 30, 2003

  
GARY BENZION, PH.D  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600